

U.S.S.N. 09/714,469
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AMENDMENT AND RESPONSE TO OFFICE ACTION

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Remarks

Rejection Under 35 U.S.C. § 102

Claims 42-49 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 5,753,782 to Hammond et al. ("Hammond"). Applicants respectfully traverse this rejection.

Hammond

Hammond discloses a polyester composition formed of a biodegradable polyester and a plasticising quantity of a plasticiser (col. 1, lines 28-42). In the relevant part, Hammond teaches that the polyester can be polyhydroxybutyrate-co-hydroxyvalerate (PHBV) (col. 1, lines 63-66). Hammond further provides a formula of the usable PHAs as $-O-C_mH_n-CO-$ in which m is 3 or 4 and $-O-C_mH_n-CO-$ **must contain a C₁ or C₂ side chain** on the carbon next to oxygen in the chain (col. 2, lines 24-35). Therefore, the formula does not encompass a 4-hydroxybutyrate unit because 4-hydroxybutyrate does not have a C₁ or C₂ side chain.

The Claimed Invention

In contrast, claims 42-29 specifically require poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB). The Examiner alleged that Hammond teaches PHB with a mixture of 3-hydryoxy and 4-hydroxy and, thus, falls within the definition of the PHA defined in any of claims 42-49. The applicants respectfully disagree. Hammond teaches

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that usable PHA thereof is preferably PHB or PHBV, which may be 3-hydroxy or 4-hydroxy or a mixture of both (col. 2, lines 57-58). PHB is defined as polyhydroxybutyrate (col. 2, line 54), and PHBV is defined as polyhydroxybutyrate-co-hydroxyvalerate (col. 2, lines 55-56). Thus, PHB is a homopolymer of hydroxybutyrate that can be 3-hydroxybutyrate (homo- poly (3-hydroxybutyrate)) or 4-hydroxybutyrate (homo- poly (4-hydroxybutyrate)). Homo- poly (3-hydroxybutyrate) and homo- poly (4-hydroxybutyrate) can be used as a mixture (col. 2, lines 57-58). Therefore, Hammond does not disclose a **copolymer** formed of both 3-hydroxybutyrate and 4-hydroxybutyrate units as required by claims 42-49. As such, Hammond does not anticipate claims 2, 4-9 and 20 under 35 U.S.C. § 102(e).

Rejection under 35 U.S.C. 103

Claims 42-49 were rejected under 35 U.S.C. 103 over Hammond. The applicants respectfully traverse the rejection. Hammond teaches that the copolymers of formula I which, as described above, cannot have 4-hydroxybutyrate units (see col. 2, lines 33-35; see also the discussion above). Moreover, Hammond teaches using plasticizers to improve the processability of the polyesters defined therein (col. 1, lines 24-27). As such, Hammond does not provide the motivation for one of ordinary skill in the art to **make and use a polymer without plasticizers to form compositions** defined in claims 42-29, which have good retention of elongation.

Moreover, the implicit premise underlying the composition described by Hammond which uses plasticizers to improve the mobility and flexibility of the polymers described therein is that the polymers described therein are not sufficiently mobile or flexible for various applications. The instant invention, however, is

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composition containing P3HB4HB in which the characteristics of the polymer itself, not that of plasticizers, provides good retention of elongation. Therefore, even if one argued that Hammond teaches using a biodegradable polymer with no plasticizers to form compositions having good processability, one of ordinary skill in the art still would not have a reasonable expectation of success. Therefore, Hammond would not render claims 42-49 *prima facie* obvious under 35 U.S.C. 103 (*see, Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986); *see also* MPEP § 2141).

The applicants honestly solicit the allowance of claims 42-49. A copy of claims as pending are attached as appendix for the Examiner's convenience.

Respectfully submitted,



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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper, along with any paper referred to as being attached or enclosed is being deposited with the United States Postal Service on the date, shown below with sufficient postage as first-class mail, to the U.S. Patent and Trademark Office, Washington, DC 20231.

Peggy D. Bailey
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Appendix: Claims As Pending

42. A polymer composition comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) and a nucleant.
43. The composition of claim 42 wherein the nucleant is boron nitride.
44. (Amended) The composition of claim 42 wherein the nucleant is present at levels from 0.1 to 20 wt% of the composition.
45. (Amended) The composition of claim 42 wherein the nucleant is present at levels from 1 to 10 wt% of the composition.
46. A method of producing a shaped polymeric object comprising melting a composition comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) and a nucleant, and producing a shaped object therefrom by extrusion, molding, coating, spinning, blowing, thermoforming or calendaring processes or combination of the processes.
47. The method of claim 46 wherein the nucleant is boron nitride.
48. A shaped object made according to claim 46.
49. A shaped object made according to claim 47.

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